SUBCHAPTER 4. LICENSING OF NATURALLY OCCURRING AND ACCELERATOR PRODUCED RADIOACTIVE MATERIALS

7:28-4.1 License required for production, transfer, receipt, acquisition, ownership, possession or use of all naturally occurring and accelerator produced radioactive materials

(a) This subchapter shall apply to persons who produce, transfer, receive, acquire, own, possess or use any naturally occurring or accelerator produced radioactive materials in this State.

(b) No person shall produce, transfer, receive, acquire, own, possess or use any radioactive substance obtained from naturally occurring materials or produced by an accelerator unless authorized by a specific State license issued by the Department, a general State license as provided in N.J.A.C. 7:28-4.5, or an exemption as provided in N.J.A.C. 7:28-4.3.

Excepted from this provision are by product source materials and special nuclear materials.

7:28-4.2 Recognition of licenses from other jurisdictions

(a) Any person who possesses a specific license or equivalent licensing document issued by a Federal agency or any other state may, pursuant to such document, transport, receive, possess, or use the radioactive materials specified in such license within this State for a period not in excess of 20 days in any period of 12 consecutive months without obtaining a specific license from the Department provided that:

1. The license does not limit the activity to specified installations or locations;

2. The licensee notifies the Department in writing at least two days prior to the time that such radioactive material is brought into this State. Such notification shall indicate the location, period, and type of proposed possession and use within this State, and shall be accompanied by a copy of the pertinent licensing document. If in a specific case the two-day period would impose an undue hardship on the user, he may, upon application to the Department, obtain permission to proceed sooner;

3. The licensee complies with all the terms and conditions of the license;

4. The licensee provides such other information as the Department may request; and

(b) The Department may withdraw, limit or qualify its acceptance of such licenses issued by another agency, or any produce distributed pursuant to such licensing documents, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

7:28-4.3 Exemption from requirement for a license for production, transfer, receipt, acquisition, ownership, possession or use of all naturally occurring and accelerator produced radioactive materials

(a) Any person is exempt from the requirement for a license for the production, transfer, receipt, acquisition, ownership, possession or use of all naturally occurring and accelerator produced radioactive materials as follows:

1. The person is a plant or laboratory owned by or operated on behalf of a Federal agency;

2. The person is a common or contract carrier and is transporting or storing radioactive materials covered by N.J.A.C. 7:28-4.7 in the regular course of carriage for another, or storage incident thereto;

3. To the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing naturally occurring or accelerator produced radioactive substances in concentrations not in excess of those exempted in N.J.A.C. 7:28-4.3(b);

4. To the extent that such person receives, possesses, uses, transfers, owns or acquires luminous timepieces or parts thereof containing radium. However, any person who desires to apply radium to luminous timepieces or parts thereof is not exempt and must obtain a specific State license;

5. Naturally occurring radioactive materials of an equivalent specific radioactivity not exceeding that of natural potassium (10-9 curies per gram of potassium);

6. If the Department, upon request by an owner or on its own initiative with the approval of the Commission, grants a specific exemption from any requirements of this subchapter should it determine that such exemption is not likely to result in unnecessary radiation.

(b) The following concentrations of radioactive substances when obtained from naturally occurring materials or when produced by an accelerator are exempt from the requirement for a license for the production, transfer, receipt, acquisition, ownership or use of all naturally occurring and accelerator produced radioactive materials:

Element (Atomic Number)	Isotope	Gas Concentration uCi/cc/a	Liquid & Solid Concentrations uCi/cc/a/a

Beryllium (4)	Be 7	--	2 x 10-2
Cadmium (48)	Cd 109	--	2 x 10-3
Carbon (6)	C 14	1 x 10-6	8 x 10-3
Chromium (24)	Cr 51	--	2 x 10-2
Cobalt (27)	Co 57	--	5 x 10-3
Hydrogen (1)	H 3	5 x 10-6	3 x 10-2
Iron (26)	Fe 55	--	8 x 10-3
Manganese (25)	Mn 52	--	3 x 10-4
Manganese (25)	Mn 54	--	1 x 10-3
Tungsten (74)	W 181	--	4 x 10-3
Vanadium (23)	V 48	--	3 x 10-4
Zinc (30)	Zn 65	--	1 x 10-3
Beta and/or gamma emitting radioactive material not listed above with half life less than 3 years	--	1 x 10-10	1 x 10-6

*Values are given only for those materials normally used as gases.

**uCi/gm for solid

1. Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in this section, the value given is that of the parent isotope and takes into account the radioactivity of the daughters.

2. For purposes of N.J.A.C. 7:8-4.3(a)4, where a combination of isotopes is involved, the limit for the combination shall be computed as follows:

    i. Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in this section for the specific isotope when not in combination. The sum of such ratios may not exceed “1” (unity).

Example:

$$\frac{\text{Prod. Conc. of Isotope A}}{\text{Exempt Conc. of Isotope A}} + \frac{\text{Prod. Conc. of Isotope B}}{\text{Exempt Conc. of Isotope B}} + \frac{\text{Prod. Conc. of Isotope C}}{\text{Exempt Conc. of Isotope C}} \leq 1$$

7:28-4.4 Types of licenses for production, transfer, receipt, acquisition, ownership, possession or use of all naturally occurring and accelerator produced radioactive materials

(a) General State licenses described in N.J.A.C. 7:28-4.5 are effective without the filing of an application with the Department or the issuance of licensing documents to particular persons.

(b) Specific State licenses are issued to named persons upon application filed pursuant to the requirements of this subchapter.

7:28-4.5 General licenses for the transfer, receipt, acquisition, ownership, possession or use of naturally occurring and accelerator produced radioactive materials and certain devices and equipment

(a) Any person who uses, transfers, receives, acquires, owns or possesses the following devices and equipment incorporating naturally occurring and/or accelerator produced radioactive material, when manufactured, tested and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Department, or a specific license of a Federal agency or any other state, shall be deemed to have a general State license:

1. Devices designed for use as static eliminators and which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of Polonium 210 or 50 microcuries of Radium 226 per device;

2. Spark gap tubes and electronic tubes which contain radioactive material consisting of not more than one microcurie of Radium per tube;

3. Devices designed for ionizing of air and which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of Polonium 210 or 50 microcuries of Radium 226 per device.

(b) The devices described in (a) above shall not be transferred, abandoned or disposed of except by transfer to a person duly authorized to receive such device by a specific State license issued by the Department, a Federal agency, or any other state.

(c) The following quantities of radioactive substances, when obtained from naturally occurring materials or when produced by an accelerator, are generally licensed provided that no person shall at any one time possess or use more than a total of 10 such quantities:

Radioactive Material	Column A Not as a Sealed Source (microcuries)	Column B As a Sealed Source (microcuries)
Beryllium (Be-7)	50	50
Bismuth 207 (Bi-207)	1	10

Cadmium 109-Silver 109		
(Cd 109/+Ag 109)	10	10
Cerium 141 (Ce-141)	1	10
Chromium 51 (Cr-51)	50	50
Cobalt 57 (Co-57)	20	20
Germanium 68 (Ge-68)	1	10
Iron 55 (Fe-55)	50	50
Manganese 52 (Mn-52)	1	10
Polonium 210 (Po-210)	0.1	1
Radium and daughters	0.1	1
Sodium 22 (Na-22)	10	10
Vanadium 48 (V-48)	1	10
Zinc 65 (Zn-65)	10	10
Beta and/or gamma emitting radioactive material not listed above	1	10

(d) There are no generally licensed quantities for alpha-emitting materials other than those set forth in N.J.A.C. 7:28-4.5(c).

(e) Any person who owns, receives, acquires, possesses or uses radioactive material when contained in a device designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition or for producing light or an ionized atmosphere, when such devices are manufactured in accordance with the specifications contained in a specific license authorizing distribution under a general license issued to the supplier by the Department, a Federal agency, or any other state, is deemed to have a general State license, provided that:

1. The device is labeled in accordance with the provisions of the specific license which authorizes the distribution of the devices;

2. The device bears a label containing the following or a substantially similar statement:

"This device contains radioactive material and has been manufactured for distribution as a generally licensed device pursuant to

_____

(identify appropriate section of the rules)

_____

(name of licensing agency and state)

License No._____by_____(name of supplier)

This device shall not be transferred, abandoned or disposed of except by transfer to a person duly authorized to receive such device by a specific license issued by the Department, a Federal agency, or any other state.

Removal of this label is prohibited."; and

3. The devices requiring special installation shall be installed on the premises of the general licensee by a person authorized to install the devices under a specific license issued to the installer by the Department, a Federal agency, or any other state.

(f) Persons who transfer, receive, acquire, own, possess or use items and quantities of radioactive materials set forth in N.J.A.C. 7:28-4.5(a) and (c) pursuant to a general State license shall not:

1. Effect an increase in the radioactivity of such scheduled items or quantities by adding other radioactive material thereto, by combining radioactive material from two or more such items or quantities, or by altering them in any other manner so as to increase the rate of radiation emission;

2. Administer or direct the adminstration of the scheduled items or quantities or any part thereof to a human being, either externally or internally, for any purpose, including, but not limited to, diagnostic, therapeutic and research purposes;

3. Add or direct the addition of the scheduled items or quantities or any part thereof to any food, beverage, cosmetic, drug or other product designed for ingestion or inhalation by, or application to, a human being; or

4. Include the scheduled items or quantities or any part thereof in any device, instrument, apparatus, including component parts and accessories intended for use in diagnosis, treatment or prevention of disease in human beings or animals or otherwise intended to affect the structure or any function of the body of human beings or animals.

(g) Persons who receive, acquire, possess or use a device pursuant to a general license specified in N.J.A.C. 7:28-4.5(a):

1. Shall not transfer, abandon or dispose of the device except by transfer to a person duly authorized to receive such device by a specific license issued by the Department, a Federal agency, or any other state:

2. Shall assure that all labels affixed to the device at the time of receipt and bearing the statement, "Removal of this label is prohibited", are maintained thereon and shall comply with the instructions contained in such labels;

3. Shall have the device tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at intervals not to

exceed six months except that devices containing only tritium need not be tested for any purpose and devices containing only krypton need not be tested for leakage;

4. Shall have the tests required by N.J.A.C. 7:28-4.5(g)3 and all other services involving the radioactive material, its shielding and containment, performed by the supplier or other person duly authorized by a specific license issued by the Department, a Federal agency, or any other state to manufacture, install or service such devices;

5. Shall maintain records of all tests performed on the devices as required under N.J.A.C. 7:28-4.5(g)3, including the dates and results of the tests and the names and addresses of the persons conducting the tests;

6. Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding or containment of the radioactive material or the on-off mechanism or indicator, shall immediately suspend operation of the device until it has been either:

   i. Repaired by a supplier, manufacturer, or other person holding a specific license issued by the Department, a Federal agency, or any other state to manufacture, install or service such devices; or

   ii. Disposed of by transfer to a person holding a specific license issued by the Department, a Federal agency, or any other state to receive the radioactive material contained in the device; and

7. Shall be exempt from the requirements of this subchapter, except the provisions of N.J.A.C. 7:28-4.4(a), 4.9, 4.14, 4.18, 8.2, 8.4, and 13.

7:28-4.6 Application for and renewal of specific State licenses for the transfer, receipt, acquisition, ownership, possession or use of naturally occurring and accelerator produced radioactive materials

(a) Upon approval of an initial or renewal application, a specific State license may be issued by the Department for a period of five years commencing on the date the license is issued.

(b) Application for specific State licenses and renewals shall be filed with the Department, on forms available from the Department.

(c) All applications shall contain the following signature and certification:

1. "I certify under penalty of law that the information provided in this document is true, accurate and complete. I am aware that there are significant civil and criminal penalties for submitting false, inaccurate or incomplete information, including fines and/or imprisonment."

2. The certification shall be signed by the highest ranking corporate, partnership, or governmental officer or official at the facility or the individual for which or for whom the specific State license is requested.

(d) An application for a specific State license may include a request for a State license authorizing one or more activities.

(e) Subject to the provisions of N.J.A.C. 7:28-4.7 and 4.8, an application for a specific State license for any human use or uses of radioactive material specified in one or more of the Human Use activity Groups I to VI inclusive listed in N.J.A.C. 7:28-4.7(b) may be approved for all of the uses within the group or groups which include the use or uses specified in the application.

(f) Information included in the specific State license application will be incorporated in and made a part of the terms and conditions of such license by reference.

(g) All applicants for initial and renewal applications for specific State licenses shall complete the application in its entirety with no reference to previously filed documents. The Department may accept photocopies of previous relevant applications.

(h) No initial or renewal specific State licenses shall be issued unless the appropriate annual license fee required by N.J.A.C. 7:28-4.18 is paid.

(i) Except as provided in N.J.A.C. 7:28-4.20, applications and documents submitted to the Department will be made available for public inspection.

(j) Upon the request of the Department at any time after the filing of the original or renewal specific State license application, and before the expiration of the license, the applicant shall submit further information to enable the Department to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(k) All applications for license or amendment shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(l) The Department may deny an application for a specific State license if the applicant:

1. Fails to comply with any provisions of the Act or any rules promulgated thereunder;
2. Falsifies or makes misleading statements in the application for license; or
3. Falsifies or makes misleading statements in any documents which were utilized to obtain a license.

7:28-4.7 General requirements for approval of an application for an initial specific State license or renewal of a specific State license for use of naturally occurring and accelerator produced materials

(a) If the Department determines that an applicant meets the requirements of this subchapter and the Act, it may issue an initial specific State license or renew a specific State license for non-human use of radioactive materials provided:

1. The applicant is qualified by reason of training and experience to use the radioactive material for the purpose requested in such manner as to protect health, minimize danger to life or property and prevent unnecessary radiation;

2. The applicant's proposed equipment, facilities and procedures are adequate to protect health, minimize danger to life or property and prevent unnecessary radiation; and

3. The applicant satisfies special requirements as may be applicable in N.J.A.C. 7:28-4.8.

(b) If the Department determines that an applicant meets the requirements of this subchapter and the Act, it may issue an initial specific State license or renew a specific State license for human use of radioactive materials for one or more of the following Human Use Groups of activities:

1. Group I: Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution and excretion. This group does not include imaging or localization studies;

2. Group II: Use of prepared radiopharmaceuticals for diagnostic imaging and localization studies;

3. Group III: Use of generators and reagent kits for the preparation and use of radiopharmaceuticals for certain diagnostic studies;

4. Group IV: Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety;

5. Group V: Use of prepared radiopharmaceuticals for certain therapeutic uses that normally require hospitalization for purposes of radiation safety; and

6. Group VI: Use of sources and devices containing radionuclides for certain medical uses.

(c) To qualify for an initial specific State license or renewal of a specific State license for human use of radioactive materials for any purpose described in Groups I through VI in (b), above the applicant must demonstrate qualification by reason of training and experience to use the radioactive material for the purpose requested

and in such manner as to protect health, minimize danger to life or property, and prevent unnecessary radiation, by satisfying the training and experience requirements for the appropriate Human Use Group of activities as follows:

1. The training and experience must have been obtained within a five year period preceding the date of the application for an initial or renewal specific State license or must be supplemented by continuing education or experience. The original training and experience should have been received in a formal residency program in an accredited medical institution. Each applicant's training and experience are examined on a case-by-case basis. If an applicant wishes to use radiopharmaceuticals but does not have the training and experience described, the applicant may submit an application listing specific qualifications and these will be considered by the Department.

2. To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Human Use Groups I, II, and/or III, an applicant shall have all the training and experience specified in (c)2i, ii and iii below;

Two hundred hours training in basic radioisotope handling techniques applicable to the use of unsealed sources. This training shall consist of lectures, laboratory sessions, discussion groups, or supervised experience in a nuclear medicine laboratory (that is, on-the-job training in a formalized training program) in the following areas and for the specific hours of class, laboratory or clinical experience:

(1) Radiation physics and instrumentation (100 hours);
(2) Radiation protection (30 hours);
(3) Mathematics pertaining to the use and measurement of radioactivity (20 hours);
(4) Radiation biology (20 hours); and
(5) Radiopharmaceutical chemistry (30 hours);

ii. Five hundred hours of experience with the types and quantities of radioactive material for which the application is being made. For authorization of Human Use Group III (generators and reagent kits), this experience shall include personal participation in five elution procedures, including testing of eluate, and in five procedures to prepare radiopharmaceuticals from Human Use Group III reagent kits; and

iii. Five hundred hours of supervised clinical training in an institutional nuclear medicine program. The clinical training shall cover all appropriate types of diagnostic procedures and shall include:

(1) Supervise examination of patients to determine the suitability for radioisotope diagnosis and recommendation on dosage to be prescribed;
(2) Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurement, and plotting data;
(3) Follow-up of patients when required; and
(4) Study and discussion with preceptor of case histories to establish most appropriate diagnostic procedures, limitation, contraindication, etc.

3. The requirements specified in (c)2i, ii and iii above may be satisfied concurrently in a three month training program if all three areas are integrated into the program.

4. Certification by the American Board of Nuclear Medicine, or the American Board of Radiology in Diagnostic Radiology with Special Competence in Nuclear Radiology, will be accepted as evidence that an applicant has had adequate training and experience to use Human Use Groups I, II, and III as specified in (c)2i, ii and iii above.

5. An applicant who wishes to be authorized for only one or two specific diagnostic procedures shall have training in basic radioisotope handling techniques and clinical procedures commensurate with the procedures and quantities of radioactive material being requested. Such requests will be examined on a case-by-case basis by the Department.

6. To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Groups IV and/or V, an applicant shall have:

    i. Eighty hours training in basic radioisotope handling techniques applicable to the use of unsealed sources for therapy procedures, consisting of lectures, laboratory sessions, discussion groups or supervised experience in the following areas and for the following specific hours:

        (1) Radiation physics and instrumentation (25 hours);
        (2) Radiation protection (25 hours);
        (3) Mathematics pertaining to the use and measurement of radioactivity (10 hours); and
        (4) Radiation biology (20 hours);

7. To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Group VI an applicant shall have:

    i. Two hundred hours training in basic radioisotope handling techniques applicable to the use of sealed sources for therapy procedures, consisting of lectures, laboratory sessions, discussion groups, or supervised experience in the following areas and for the following specified hours:

        (1) Radiation physics and instrumentation (110 hours);
        (2) Radiation protection (40 hours);
        (3) Mathematics pertaining to the use and measurements of radioactivity (25 hours); and
        (4) Radiation biology (25 hours);

    ii. Five hundred hours experience with the types and quantities of radioactive material for which the application is made;

    iii. Clinical training in Group VI procedures consisting of active practice in therapeutic radiology with a minimum of three years experience of which at least one year shall have been spent in a formal training program accredited by the Residency Review Committee of Radiology and the Liaison Committee on Graduate Medical Education; and

    iv. Evidence of certification by the American Board of Radiology in Radiology or Therapeutic Radiology, certification as a British “Fellow of the Faculty of Radiology” (FFR) or “Fellow of the Royal College of

Radiology" (FRCR), or Canadian certification from the Royal College of Physicians and Surgeons (RCPS) in therapeutic radiology may be submitted in lieu of the training required in (c)7i and iii above.

8. In addition to the training required by (c)7 above, an applicant for a license for Human Use Group VI activities shall demonstrate that its proposed equipment, facilities and procedures are adequate to protect health, minimize danger to life or property and prevent unnecessary radiation; and

9. An applicant for a license for Human Use Group VI activities shall satisfy special requirements as may be applicable in N.J.A.C. 7:28-4.8.

7:28-4.8 Special requirements for approval of an application for an initial specific State license or renewal of a specific State license for use of naturally occurring and accelerator produced radioactive materials

(a) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued for human use of radioactive materials by an institution provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant has appointed a medical isotopes committee to evaluate all proposals for research, diagnosis, and therapeutic use of radioactive material within that institution. Membership of the committee shall include one authorized user for each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer;

3. The applicant possesses adequate facilities for the clinical care of patients;

4. The physician(s) designated on the application as the individual user(s) has considerable pertinent training and experience in the use, handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients; and

5. If the application is for a specific State license to use unspecified quantities of multiple types of radioactive materials, the applicant's staff has had substantial pertinent experience in using a variety of radioactive materials for various human uses.

(b) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued for human use of radioactive materials by a physician or dentist provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patient whenever it is advisable; and

3. The applicant has had extensive training and supervised experience in the proposed use, the handling and administration of radioisotopes and, where applicable, the clinical management of radioactive patients. The applicant shall furnish suitable evidence of such experience with his application. A statement from the institution where the applicant acquired the training and experience, indicating its amount and nature, may be submitted as evidence of such experience.

(c) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued for human use of a sealed source of radioactive materials provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant or, if the application is made by an institution, the individual user(s) has specialized training in therapeutic use of the radioactive device considered or has experience equivalent to such training; and

3. The individual user is a physician or dentist.

(d) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued for use of multiple quantities or types of radioactive material in research and development provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant's staff has had substantial training and experience with a variety of radioisotopes for various research and development uses;

3. The applicant has established an isotope committee, composed of a radiological safety officer, a representative of management and one or more persons trained or experienced in the safe use of radioactive materials, which will review and approve or disapprove proposals for use of radioactive materials in the advance of purchase of such materials; and

4. The applicant has appointed a radiological safety officer who shall be responsible for rendering advice and assistance on radiological safety.

(e) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued for use of multiple quantities or types of radioactive material in processing for distribution to other authorized persons provided:

1. The applicant satisfies the general requirements for approval of specific State license application in N.J.A.C. 7:28-4.7;

2. The applicant's staff has had training and experience in the processing and distribution of a variety of radioisotopes; and

3. The applicant has appointed a radiological safety officer who shall be responsible for rendering advice and assistance on radiological safety.

(f) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued to distribute certain devices to persons generally licensed under N.J.A.C. 7:28-4.5(a) and

(e) provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant submits sufficient information relating to the design, manufacturer prototype testing, quality control procedures, labeling, proposed uses and potential hazards of the device to provide reasonable assurance that:

i. The radioactive material contained in the device cannot be easily removed from the device;

ii. No person possessing, using, transporting or exposed to the device will receive a radiation dose to a major portion of his body in excess of 0.5 rem in any one year under ordinary circumstances of use;

iii. The device can be safely operated by persons not having training in radiological protection; and

iv. The radioactive material within the device would not be accessible to unauthorized persons; and

3. In describing the label or lables and contents thereon to be affixed to the device, the applicant shall separately indicate those instructions and precautions which are necessary to assure safe operation of the device. Such instructions and precautions shall be contained on labels as described in N.J.A.C. 7:28-4.5(e).

(g) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued for use of a sealed source or sources of radioactive materials in industrial and nonmedical radiography provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant has an adequate program for training radiographers and radiographers' assistants and submits to the Department a schedule or description of such program which specifies the following:

   i. Initial training;
   ii. Periodic training;
   iii. On-the-job training;
   iv. Means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with the requirements of this subchapter, the specific licensing requirements, and the operating and emergency instructions of the applicant; and
   v. Means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant;

3. The applicant has established and submitted to the Department satisfactory written operating and emergency instructions as prescribed by N.J.A.C. 7:28-17;

4. The applicant will have an adequate internal inspection system, or other management control, providing assurance that the requirements of this chapter, the specific State license provisions, and the applicant's operating and emergency instructions are followed by radiographers and radiographers' assistants;

5. The applicant submits a description of its overall organizational structure pertaining to the radiography program, including specified delegation of authority and responsibility for operation of the program; and

6. The applicant who desires to conduct his own leak tests has established adequate procedures to be followed in leak testing sealed sources for possible

leakage and contamination and submits to the Department a description of such procedures, including:

i. Instrumentation to be used;
ii. Method of performing test (for example, points on equipment from where wipe samples will be taken and method of obtaining the wipe sample); and
iii. Pertinent experience of the person who will perform the test.

(h) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license will be issued to transfer, possess, or control products or materials containing exempt concentrations of radioactive material specified in N.J.A.C. 7:28-4.3(b) which the transferor has introduced into the product or material provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant submits:

i. A description of the product or material into which the radioactive material will be introduced;
ii. The intended use of the radioactive material and the product into which it is introduced;
iii. The method of introduction;
iv. The initial concentration of the radioactive material in the product or material;
v. The control methods to assure that no more than the specified concentration is introduced into the product or material;
vi. The estimated time interval between introduction and transfer of the product or material; and
vii. The estimated concentration of the radioisotope in the product or material at the time of proposed transfer by the applicant;

3. The applicant provides:

i. Reasonable assurance that the concentrations of the radioactive material at the time of transfer will not exceed the exempt concentrations listed in N.J.A.C. 7:28-4.3(b);
ii. That reconcentration of the radioactive material in concentrations exceeding those exempted under N.J.A.C. 7:28-4.3(b) is not likely;
iii. That the product or material is not likely to be inhaled or ingested; and
iv. That use of the lower concentration(s) is not feasible; and

4. Within 30 days subsequent to the end of the reporting period, each licensee shall file an annual report with the Department describing the kinds and

quantities of products transferred, the concentration of radioactive material contained and the quantity of radioactive material transferred during the reporting period which shall be the 12 month period ending June 30 of each calendar year.

(i) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued to distribute certain devices to persons specifically licensed under N.J.A.C. 7:28-4.7 provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling, proposed uses and potential hazards of the device to provide reasonable assurance that:

   i. The radioactive material contained in the device cannot be easily removed;
   ii. The device can be safely operated by persons having trained in radiological protection; and
   iii. The radioactive material within the device would not be accessible to unauthorized persons; and

3. Each device distributed as authorized by such license is to bear a label containing the following or substantially similar statements:

   i. "Caution Radioactive Materials";
   ii. The isotope name;
   iii. The isotope quantity and date; and
   iv. The following statement:

   "This device contains radioactive material and has been manufactured for distribution as a specifically licensed device pursuant to
   _____
   (identify appropriate section of the regulation)
   _____
   (name of licensing agency and state)
   License No._____by_____(name of supplier)
   Disposal of this device shall conform to the requirements listed in N.J.A.C. 7:28-4.5(g)6ii of the Radiation Protection Code
   Removal of this label is prohibited."

7:28-4.9 Terms and conditions of general and specific Statelicenses

(a) Each State license issued pursuant to this subchapter shall be subject to all the provisions of the Act, now or hereafter in effect, and to this chapter and orders of the Department.

(b) No license to possess or utilize radioactive material pursuant to this subchapter shall be transferred or assigned.

(c) Each person licensed by the Department pursuant to this subchapter shall confine his/her possession and use of radioactive material to the locations and purposes authorized by such license, and shall not use or permit the use of radioactive materials contrary to the applicable requirements of this chapter. Persons licensed under the provisions of this subchapter may transfer radioactive material within the State only to the persons licensed to receive such material or as otherwise authorized by the Department in writing.

(d) The Department may incorporate in any State license at the time of issuance, or thereafter, all such additional requirements and conditions with respect to the licensee's receipt, possession, use or transfer of radioactive material as it deems appropriate or necessary in order to assure compliance with this chapter and the Act.

(e) Each licensee authorized under N.J.A.C. 7:28-4.8(f) to distribute certain devices to generally licensed persons shall:

1. Report to the Department all transfers of such devices to persons in New Jersey generally licensed under N.J.A.C. 7:28-4.5(a) and (c). Such report shall identify each general licensee by name and address, the type and number of device(s) transferred, and the quantity and kind of radioactive material contained in each device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to generally licensed persons; and

2. Furnish to each general licensee to whom such device is transferred a copy of N.J.A.C. 7:28-4.5(a), (e) and (g), 8.2 and 8.4.

(f) Each licensee authorized under N.J.A.C. 7:28-4.8(i) to distribute certain devices to specifically licensed persons shall:

1. Report to the Department all transfers of such devices to persons in New Jersey specifically licensed under N.J.A.C. 7:28-4.7 and 4.8. Such report shall identify each specific licensee by name and address, the type and number of device(s) transferred, and the quantity and kind of radioactive material contained each device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to specifically licensed persons.

7:28-4.10 Expiration of specific State license

Except as provided in N.J.A.C. 7:28-4.11, each specific State license shall expire at 12:01 A.M. of the day, in the month and year stated in the license.

7:28-4.11 Status of specific State licenses pending renewal

In any case in which a licensee has filed a complete application in proper form for renewal of a specific State license not less than 30 days prior to expiration of the existing license, such license and all its existing conditions shall not expire until the Department has acted upon the application.

7:28-4.12 Amendment of a specific State license at request of licensee

(a) Applications for amendment of a specific State license shall be filed in accordance with N.J.A.C. 7:28-4.6 and shall specify the amendment desired and the grounds for such amendment.

(b) The Department will evaluate only amendment applications submitted by personnel authorized by the licensee.

(c) The applicant for an amended specific State license shall not engage in the activities for which an amendment has been requested until approval has been granted by the Department.

7:28-4.13 Records

All persons licensed pursuant to this subchapter shall keep records in accordance with N.J.A.C. 7:28-8.

7:28-4.14 Inspections

(a) All licensees shall allow the Department or its agents to inspect radioactive material and the facilities and premises where radioactive material is used or stored.

(b) No person shall prevent, prohibit, obstruct, hinder, delay or interfere with personnel of this Department or its agents in performing their duties.

(c) Upon request by the Department, or its agents licensees shall make available for inspection by the Department records kept pursuant to this chapter.

7:28-4.15 Tests

(a) At the request of the Department or its agents, each licensee shall perform, or allow the Department to perform if the Department so desires, such tests as the Department deems appropriate or necessary for the administration of this subchapter, including tests of the following:

1. Radioactive material;
2. Facilities where radioactive material is utilized or stored;
3. Radiation detection and monitoring instruments; and

4. Equipment and devices used in connection with the utilization or storage of radioactive material.

7:28-4.16 Modification, revocation, suspension, and termination of general and specific State licenses

(a) Each general State license shall be subject to modification, suspension or revocation by reason of amendments to the Act, adoption of rules by the Commission or the Department, orders issued by the Department pursuant to authority of the Act, or for violation or failure to observe any of the terms and provisions of the Act, license or any rule of the Commission or the Department, or order of the Department.

(b) Each specific State license shall be subject to modification, suspension or revocation by reason of:

1. Amendments to the Act;
2. Adoption of rules by the Commission;
3. Orders issued by the Department pursuant to the authority of the Act;
4. Conditions revealed by the application for a specific State license or statement of fact or any report, records or inspection or other means which would warrant the Department to refuse to grant a specific State license on an original application;
5. Violation of or failure to observe any of the terms and provisions of the Act or the license, or any rule of the Commission or Department or order of the Department;
6. Falsification or misleading statements in any license application;
7. Alteration of licensing document;
8. Falsification of required records; or
9. Failure to make timely payment of licensing fees.

(c) If a specific State license is not to be renewed or if a licensee requests a termination of its license, the licensee shall furnish to the Department, prior to the expiration date of the license, close-out surveys and/or wipe tests of the facility and a disposition certificate attestng to the disposal of radioactive material.

7:28-4.17 Requests for an adjudicatory hearing

(a) When the Department denies an initial application for or renewal of a specific State license, or determines to modify, revoke, suspend or terminate a general or specific State license, the Department shall send a notice of decision to the applicant or licensee by certified mail return receipt requested. The notice shall advise the applicant or licensee of the right to request a contested case hearing pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and the New Jersey Uniform Administrative Procedure Rules, N.J.A.C. 1:1-1 et seq. The notice shall include the following information:

1. Where and whom hearing requests should be sent;

2. The deadline by which hearing requests must be submitted;
3. The information that is required to be in the hearing request under (c) below; and
4. The requirements for requesting a stay under N.J.A.C. 7:28-4.18.

(b) All requests for a contested case hearing must be received by the Department within 30 calendar days of the date upon which the notice of decision was received.

(c) All requests for a contested case hearing shall be submitted in writing to the Department and shall contain:

1. The name, address and telephone number of the person making such request;

2. A statement of the legal authority and jurisdiction under which the request for a hearing is made;

3. A brief and clear statement of specific facts describing the Department decision appealed from as well as the nature and scope of the interest of the requestor in such decision; and

4. A statement of all facts alleged to be at issue and their relevance to the Department decision for which a hearing is requested. Any legal issues, associated with the alleged facts at issue, must also be included.

(d) The Department shall determine whether any request for a contested case hearing should be granted. In making such determination, the Department shall evaluate the request to determine whether a contested case, as defined by the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., exists and whether there are issues of fact which, if assumed to be true, might change the Department's decision. Where only issues of law are raised by a request for a hearing, the request will be denied. Denial by the Department of a request for a contested case hearing shall constitute the final decision of the Department for the purposes of judicial appeal.

7:28-4.18 Requirements governing requests for stay of the effective date of the Department decision for which an adjudicatory hearing is requested

(a) The Department may grant a stay of the effective date of a decision to deny, modify, revoke or suspend any license. The applicant for such a stay must submit evidence that one of the following circumstances exist:

1. The granting of such stay is required as a constitutional or statutory right; or

2. The potential impact on public health, safety, welfare or the environment which might result from a decision to grant a stay is greatly outweighed by immediate, irreparable injury to the specific party requesting such stay.

(b) The decision to grant a contested case hearing request shall not automatically result in a stay of the Department action appealed from absent an express decision to stay such action by the Director. The burden shall be upon the party requesting a hearing to explicitly request a stay of action within the same document as well as to disclose reasons why such stay should be granted.

(c) Department decisions are effective, according to their terms, unless stayed by the Department in writing, upon receipt of written request pursuant to this section.

(d) Written requests for a stay of the effective date of the Department's decision must be made to the Department within 30 calendar days of the date upon which the notice of decision was received.

(e) Any stay that is granted by the Department shall be temporary and in no case shall it extend beyond the date of the Department's final decision of the contested case.

(f) Determinations made pursuant to this section shall be made in a writing mailed to the specific party making such request.

7:28-4.19 Specific State license fee schedule for the production, transfer, receipt, acquisition, ownership, possession or use of naturally occurring or accelerator produced radioactive material

(a) The specific State license fee schedule for the production, transfer, receipt, acquisition, ownership, possession or use of naturally occurring or accelerator produced radioactive materials is as follows:

****FEE SCHEDULE OMITTED****

(b) All licensees shall pay the fees set forth in (a) above by check payable to "Treasurer, State of New Jersey" prior to August 1 of each year.

1. In the event that the fees are paid after August 1, a delinquency fee equal to one-half of the annual license fee will be imposed. Failure to pay an annual license fee including any accrued delinquency fees for longer than 90 days shall constitute grounds for suspension or revocation of the license pursuant to N.J.A.C. 7:28-4.16.
2. The annual license fee shall be mailed to:

State of New Jersey
Department of Environmental Protection
Board of Revenue
428 East State Street
Trenton, New jersey 08625-0402

(c) Facilities for which multiple license categories apply shall be charged the sum of the fees for each of the applicable categories.

(d) The term “doses per year” when used in (a) above means the number of doses of radioactive materials within a category that are administered during the period July 1 to June 30.

(e) The term “human use group” when used in (a) above includes the use oc radioactiver material for calibration and quality control procedures as well as the administration of radioactive materials to humans.

7:28-4.20 Confidentiality claims

(a) Any applicant required to submit any information pursuant to the Act or this chapter which in the applicant’s opinion constitutes trade secrets, proprietary information or information related to national security, may assert a confidentiality claim by following the procedures set forth in this subchapter.

(b) Any applicant submitting any information to the Department and asserting a confidentiality claim covering any information contained therein shall submit two documents to the Department. One shall contain all the information required by the Act or this chapter including any information which the applicant alleges to be entitled to confidential treatment. The second shall be identical to the first except that it shall contain no information which the applicant alleges to be entitled to confidential treatment. The second can be a photocopy of the first, with the allegedly confidential material blacked out.

(c) The top of each page of the first submission containing the information which the applicant alleges to be entitled to confidential treatment shall display the heading “CONFIDENTIAL” in bold type, or stamp.

(d) All parts of the text of the first submission which the applicant alleges to be entitled to confidential treatment shall be underscored or highlighted in a clearly identifiable manner. This manner of marking confidential information shall be such that both the allegedly confidential information and the underscoring or highlighting is reproducible on photocopying machines.

(e) The first submission, containing the information which the applicant alleges to be entitled to confidential treatment, shall be sealed in an envelope which shall display the word “CONFIDENTIAL” in bold type or stamp on both sides. This envelope, together with the second, non-confidential submission (which may or may not be enclosed in a separate envelope, at the option of the applicant), shall be enclosed in another envelope for transmittal to the Department. The outer envelope shall bear no marking indicating the confidential nature of the contents.

(f) To ensure proper delivery, the complete package should be sent by certified mail, return receipt requested, or by other means which will allow verification of receipt. Ordinary mail may be used, but the Department will assume no responsibility for packages until they are actually received.

7:28-4.21 Access to information; non-disclosure

(a) Until such time as a final confidentiality determination has been made, access to any information for which a confidentiality claim has been made will be limited to Department employees whose activities necessitate such access and as provided at N.J.A.C. 7:28-4.24 and 4.26.

(b) No disclosure of information for which a confidentiality claim has been asserted shall be made to any other persons except as provided in this subchapter.

(c) Nothing in this section shall be construed as prohibiting the incorporation of confidential information into cumulations of data subject to disclosure as public records, provided that such disclosure is not in a form that would foreseeably allow persons, not otherwise having knowledge of such confidential information, to deduce from it the confidential information or the identity of the owner or operator who supplied it to the Department.

7:28-4.22 Confidentiality determinations

(a) Information for which a confidentiality claim has been asserted will be treated by the Department as entitled to confidential treatment, unless the Department determines that the information is not entitled to confidential treatment as provided in this section and N.J.A.C. 7:28-4.23.

(b) The Department shall act upon a confidentiality claim and determine whether information is or is not entitled to confidential treatment whenever the Department:

1. Receives a request under N.J.S.A. 47:1A-1 et seq. to inspect or copy such information; or
2. Desires to determine whether information in its possession is entitled to confidential treatment; or
3. Desires for any reason in the public interest to disclose the information to persons not authorized by this subchapter to have access to confidential information.

(c) The Department shall make the initial determination whether information is or is not entitled to confidential treatment.

1. If the Department determines that information is not entitled to confidential treatment, it shall so notify the applicant who submitted the information.

2. The notice required under this subsection shall be sent by certified mail, return receipt requested and shall state the reasons for the Department's initial determination.

3. An applicant who wishes to contest a determination by the Department shall, within 30 days of notification of the determination, submit evidence to support the applicant's contention that the Department's initial determination was incorrect. The evidence may include, but need not be limited to, a statement indicating:

    i. The period of time for which confidential treatment is desired by the applicant (for example, until a certain date, until the occurrence of a specified event, or permanently);

    ii. The measures taken by the applicant to guard against undesired disclosure of the information to others;

    iii. The extent to which the information has been disclosed to others, and the precautions taken in connection therewith; and

    iv. The extent of which disclosure of the information would result in substantial damage to the applicant, including a description of the damage, an explanation of why the damage would be substantial, and an explanation of the causal relationship between disclosure and the damage.

4. Failure of an applicant to furnish timely comments or exceptions waives the applicant's confidentiality claim.

5. The applicant may assert a confidentiality claim to any information submitted to the Department by an applicant as part of its comments pursuant to (c)4 above.

6. The Department may extend the time limit for submitting comments pursuant to (c)4 above for good cause shown by the applicant and upon receipt of a request in writing.

(d) After receiving the evidence, the Department shall review its initial determination and make a final determination.

1. If, after review, the Department determines that the information is not entitled to confidential treatment, the Department shall so notify the applicant by certified mail, return receipt requested. The notice shall state the basis for the determination, that it constitutes final agency action concerning the confidentiality claim, and that the Department shall make the information available to the public on the 14th day following receipt by the applicant of the written notice.

2. If, after review, the determination is made that information is entitled to confidential treatment, the information shall not be disclosed, except as otherwise provided by this subchapter. The applicant shall be notified of the

Department's determination by certified mail, return receipt requested. The notice shall state the basis for the determination and that it constitutes final agency action.

7:28-4.23 Substantive criteria for use in confidentiality determinations

(a) When the applicant satisfies each of the following substantive criteria, the Department shall determine that the information for which a confidentiality claim has been asserted is confidential:

1. The applicant has asserted a confidentiality claim which has not expired by its terms, been waived or withdrawn;

2. The applicant has shown that reasonable measures have been taken to protect the confidentiality of the information and that the applicant intends to continue to take such measures;

3. The information is not, and has not been, available or otherwise disclosed to other persons without the applicant's consent (other than by subpoena or by discovery based on a showing of special need in a judicial or quasi-judicial proceeding, as long as the information has not become available to persons not involved in the proceeding);

4. No statute specifically requires disclosure of the information; and

5. The applicant has shown that disclosure of the information would be likely to cause substantial damage to its competitive position.

7:28-4.24 Disclosure of confidential information to other public agencies

(a) The Department may disclose confidential information to persons other than Department employees only as provided in this section or N.J.A.C. 7:28-4.25.

(b) The Department may disclose confidential information to any other State agency or to a Federal agency if:

1. The Department receives a written request for disclosure of the information from a duly authorized officer or employee of the other agency;

2. The request sets forth the official purpose for which the information is needed;

3. The Department notifies the other agency of the Department's determination that the information is entitled to confidential treatment, or of any unresolved confidentiality claim covering the information;

4. The other State or Federal agency has first furnished to the Department a written formal legal opinion from the agency's chief legal officer or counsel stating that under applicable law the agency has the authority to compel the

person who submitted the information to the Department to disclose such information to the other agency; and

5. The other agency agrees not to disclose the information further unless:

   i. The other agency has statutory authority both to compel production of the information and to make the proposed disclosure; or

   ii. The other agency has obtained the consent of the affected owner or operator to the proposed disclosure; and

6. The other agency has adopted regulations or operates under statutory authority that will allow it to preserve confidential information from unauthorized disclosure.

(c) Except as otherwise provided at N.J.A.C. 7:28-4.25, the Department shall notify in writing the applicant who supplied the confidential information of:

1. Its disclosure to another agency;
2. The date on which disclosure was made;
3. The name of the agency to which disclosed; and
4. A description of the information disclosed.

7:28-4.25 Disclosure by consent

(a) The Department may disclose any confidential information to any person if it has obtained the written consent of the applicant to such disclosure.

(b) The giving of consent by an applicant to disclose shall not be deemed to waive a confidentiality claim with regard to further disclosures unless the authorized disclosure is of such a nature as to make the disclosed information accessible to the general public.

7:28:4.26 Disclosure based on imminent and substantial danger

(a) Upon a finding that disclosure of confidential information would serve to alleviate an imminent and substantial danger to public health and the environment, the Department may:

1. Prescribe and make known to the applicant such shorter comment period (N.J.A.C. 7:28-4.22(c)4, post-determination waiting period (N.J.A.C. 7:28-4.22(d)1), or both, as it finds necessary under the circumstances; or

2. Disclose confidential information to any person whose role in alleviating the danger to public health and the environment necessitates that disclosure. Any such disclosure shall be limited to information necessary to enable the person to whom it is disclosed to carry out the activities in alleviating the danger.

(b) Any disclosure made pursuant to this section shall not be deemed a waiver of a confidentiality claim, nor shall it of itself be grounds for any determination that information is no longer entitled to confidential treatment.

7:28-4.27 Security procedures

(a) Submissions to the Department pursuant to the Act and this chapter will be opened only by persons authorized by the Department engaged in administering the Act and this chapter.

(b) Only those Department employees whose activities necessitate access to information for which a confidentiality claim has been made, shall open any envelope which is marked “CONFIDENTIAL”.

(c) All submissions entitled to confidential treatment as determined at N.J.A.C. 7:28-4.22 shall be stored by the Department only in locked cabinets.

(d) Any record made or maintained by Department employees which contains confidential information shall contain appropriate indicators identifying the confidential information.

7:28-4.28 Wrongful access or disclosure; penalties

(a) A person shall not disclose, seek access to, obtain or have possession of any confidential information obtained pursuant to the Act or this chapter, except as authorized by this subchapter.

(b) Every Department employee who has custody or possession of confidential information shall take appropriate measures to safeguard such information and to protect against its improper disclosure.

(c) A Department employee shall not disclose, or use for his or her private gain or advantage, any information which came into his or her possession, or to which he or she gained access, by virtue of his or her official position of employment or contractual relationship with the Department.

(d) If the Department finds that any person has violated provisions of this subchapter, it may:

1. Commence a civil action in Superior Court for a restraining order and an injunction barring that person from further disclosing confidential information.

2. Pursue any other remedy available by law.

(e) In addition to any other penalty that may be sought by the Department, violation of this subchapter by a Department employee shall constitute grounds for dismissal, suspension, fine or other adverse personnel action.

(f) Use of any of the remedies specified under this section shall not preclude the use of any other remedy.